

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Krukonis et al.	Art Unit:	1731
Serial No.:	10/623,006	Examiner:	Dionne W. Mayes
Filed:	July 18, 2003	Customer No.:	21559
		Confirmation No.:	4588
Title:	REDUCTION OF CONSTITUENTS IN TOBACCO		

PRE-APPEAL BRIEF REQUEST FOR REVIEW

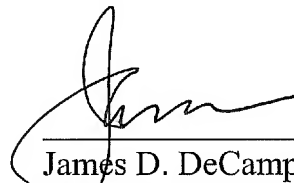
Applicant requests review of the final rejection in the above-identified application.

No amendments are being filed with this request. This request is being filed with a Notice of Appeal.

The review is requested for the reasons stated on the attached sheets.

Respectfully submitted,

Date: 25 October 2006



James D. DeCamp, Ph.D.  
Reg. No. 43,580

Clark & Elbing LLP  
101 Federal Street  
Boston, MA 02110  
Telephone: 617-428-0200  
Facsimile: 617-428-7045

## REMARKS

Claims 1–37 were deemed obvious over U.S. Patent 2,128,043 (Garner) (Final Action, April 2006, “FA”). Obviousness requires that the Office establish a *prima facie* case prior to shifting the burden to Applicants (M.P.E.P. § 2142). For the following reasons, the Office has not met its burden in this case.

In its Final Action, the Office (FA, p.2) states:

Garner discloses nearly all that is recited in the claims since it teaches a process of nicotine extraction.

The Office (FA, p.3) also assumes:

the same method that removes nicotine would also remove the other claimed constituents since the process can utilize liquid propane, [as] the extraction solvent, which is the same liquid used by Applicant which accomplishes the removal of the claimed constituents.

The specification of the present invention has clearly defined the term “constituent” as “secondary alkaloids and polycyclic aromatic hydrocarbons (PAH) found in tobacco” (page 4, lines 7-8). Consistent with this definition, Applicants previously noted that nicotine is not a constituent, as the term is used in the instant claims (Reply, Sept. 2006, “Reply”). Nicotine is well known in the art to be a “primary alkaloid.”

Applicants assert that Garner provides no suggestion, implicitly or explicitly, for the processes set forth in claims 1-37, which extract “constituents” from tobacco. As such, all of the limitations of the present claims are not contained within the Garner reference.

In addition, Applicants noted that claim 1 recites the use of a subcritical fluid consisting of carbon dioxide or a hydrocarbon (Reply, p.4), and presented data proving that use of the same solvent does not imply that the same chemicals will be extracted from tobacco under all circumstances (Reply, p.6 and p.7). The Office merely points to how Garner can be used to read on the claimed invention,

rather than pointing to specific information contained in Garner that suggests the claimed invention. The Office has accordingly failed to make Graham factor findings (MPEP § 2141) that support its obviousness conclusion. On this basis alone, Garner is properly disregarded and the § 103 rejection should be withdrawn.

In its Advisory Action, the Office made clear that it did not agree with Applicants' assertion that there is no evidence that a process that reduces or removes nicotine-(a primary alkaloid) would necessarily result in a reduction or removal of PAH's and/or secondary alkaloids (Advisory Action; October 2006, "AA"). The Office stated:

[t]he Examiner believes that alkaloids are water-soluble tobacco components that would necessarily be removed (if only a negligible amount which would satisfy the claims) during the extraction process involving a hydrocarbon solvent" (AA).

The Office did not, however, explain what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested modifying the Garner teaching to arrive at the claimed invention. Such an unsupported belief cannot provide the basis to support the Office's position.

In addition, the Office has asserted that removal of an alkaloid from tobacco in a negligible amount is sufficient to "satisfy" the instant claims. This assertion is incorrect. Applicants first note that independent claims 3 and 4 do not require the reduction of any alkaloid, but instead require reduction of a PAH. Thus, the Office's arguments with respect to these claims are not relevant. The Office has never provided any reasoning or evidence to indicate why removal of nicotine (a primary alkaloid) would necessarily result in the removal of PAHs. The Office merely assumes that one solvent will always extract the claimed constituents no matter the conditions. Applicants presented experimental data, however, proving that the conditions of the extraction do determine what compounds will be extracted from tobacco (Reply, p.6 and p.7). The Office dismissed these data as failing "to prove that the only alkaloids that would be removed via hydrocarbon extraction would be nicotine [primary alkaloids]" (AA). As shown in Table 3 in the specification, the pH and moisture content are two parameters that can be

altered to control the type and amount of constituents (*e.g.*, primary vs. secondary alkaloids or PAHs) removed from tobacco. Thus, Applicants have proven that the Office's principal premise (*i.e.*, that the same solvent must always dissolve the same constituents) is simply incorrect. Accordingly, the Office has no basis for believing that the Garner reference teaches or suggests the limitations of these claims.

In addition, claim 1 is directed to a method of reducing an amount of a constituent in tobacco by employing a subcritical fluid *consisting of* – not comprising – carbon dioxide or a hydrocarbon (see M.P.E.P. § 2111.03). As noted in the Reply (p.4), Garner makes no mention whatsoever of contacting tobacco with a subcritical fluid of carbon dioxide. Also, Garner, at best, teaches a *mixture* of anhydrous ammonia and a hydrocarbon (col. 1, lines 18-26, col 2, lines 9-33, and claim 1). That is, Garner never contacts tobacco with either of the possible subcritical fluids recited in claim 1. Indeed, Garner explicitly teaches and claims a process of extracting nicotine, which includes freeing the nicotine from its salts by means of an acid neutralizing reagent, and subsequently dissolving it in a liquefied, normally gaseous hydrocarbon. The Office did not address this critical difference between claim 1 and the Garner reference. The Office has therefore failed to consider the Garner reference as a whole – including those portions that lead away from the claimed invention, as required by M.P.E.P. § 2141.03. The Office also failed to point to any teaching or suggestion in Garner to employ a hydrocarbon not mixed with ammonia or to provide a motivation to modify the Garner reference to produce the invention of claim 1.

Claims 2 and 4 recite methods of selectively reducing an amount of a secondary alkaloid or PAH *relative* to a primary alkaloid in tobacco. With respect to these claims, the Office has never provided any motivation from Garner to produce the claimed methods. Applicants note that Garner is directed to a method of removing nicotine from tobacco, and in order to support its position, the Office must explain why the skilled artisan reading Garner would be motivated to employ a method designed to remove secondary alkaloids or PAHs preferentially over primary alkaloids, such as nicotine.

Applicants assert that such motivation cannot be found in Garner because the purpose of Garner is to remove nicotine from tobacco (col. 1, lines 1-17). Accordingly, it can provide no basis for an extraction method that selectively retains primary alkaloids.

The Office has also never provided any motivation to produce the method of claim 5 or pointed out where Garner teaches or suggests the claimed limitations. Claim 5 recites a method of reducing an amount of a constituent in tobacco that includes providing a system including a plurality of connected vessels containing tobacco. The method further includes extracting a constituent from tobacco in a first vessel using a subcritical fluid and then moving that fluid to a second vessel containing tobacco. Thus, claim 5 is directed to an extraction process that allows for continued extraction of multiple portions of tobacco. These limitations were never considered by the Office. Accordingly, the invention of claim 5 as a whole was not considered when making the rejection. This rejection as well should be withdrawn.